

Commonwealth of Pennsylvania



DEPARTMENT OF AGRICULTURE

August 25, 1999

Dr. Morris E. Potter, Director
Center for Food Safety and Applied Nutrition
U.S. Department of Health & Human Services
Food and Drug Administration
Washington, DC 20204

Dear Dr. Potter:

This letter is to indicate my interest in attending the August 26, 1999 meeting to discuss a farm-to-table approach to shell egg and egg product safety.

As Secretary Hayes described in his July 29, 1999 letter to Secretary Shalala (enclosed), Pennsylvania through its development of the Pennsylvania Egg Quality Assurance Program (PEQAP) has been successful in reducing the number of human SE isolation rates in the Mid-Atlantic States.

I would like to express our interest in having current Salmonella Enteritidis risk reduction programs considered exempt from the proposed FDA label statement.

I look forward to providing this input on August 26, 1999. If you have any questions, please contact me at 717/787-4626.

Sincerely,

A handwritten signature in black ink, appearing to read "CHR/H", written over a horizontal line.

Christian R. Herr

96P-0418

Christian R. Herr
Deputy Secretary for Regulatory Programs

LET 3

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Commonwealth of Pennsylvania



DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

SAMUEL E. HAYES, JR.

July 29, 1999

The Honorable Donna Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 615F - Hubert Humphrey Building
Washington, DC 20201

Dear Secretary Shalala:

This letter is in response to FDA's proposal to require handling instructions on all shell eggs without regard for salmonella enteritidis risk reduction programs.

The Pennsylvania Egg Quality Assurance Program (PEQAP) was implemented in 1994 to reduce the risk of salmonella enteritidis in shell eggs. There has been a sharp reduction in salmonella enteritidis isolation rates per 100,000 population in Pennsylvania, Maryland, New Jersey, and New York. PEQAP flocks in Pennsylvania were the principal suppliers of eggs to these states. PEQAP contributed to this combined 49.4% reduction of human Salmonella enteritidis rates in the Mid-Atlantic States. Over 80% of the eggs produced in Pennsylvania are enrolled in the PEQAP program.

PEQAP is a voluntary program administered by the Penn Ag Poultry Council, created by the egg industry, and monitored by the PA Department of Agriculture. The PA Department of Health serves as an advisor to the program and FDA provides additional support. The Pennsylvania Animal Diagnostic Laboratories at Penn State University, the University of Pennsylvania New Bolton Center, and the PA Department of Agriculture provide laboratory testing of eggs and environmental samples.

The PEQAP guidelines cover egg production and assure the commitment of the producer to implement the best management and monitoring practices most likely to prevent salmonella enteritidis contamination. Basic measures following HACCP principles

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include continuous environmental testing of layers and pullet houses, buying only SE-negative chicks, utilizing an intensively monitored rodent control program, and cleaning and disinfecting between flocks. Any positive eggs, eggs that are found to contain the salmonella enteritidis organism, are automatically diverted to a pasteurizing facility and then removed from the table egg market.

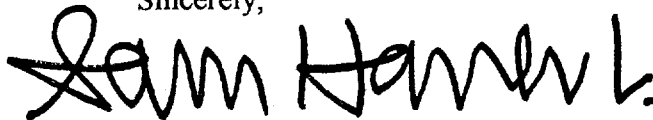
On behalf of the PEQAP members which produce over 80% of Pennsylvania eggs, I request recognition of this proven risk reduction program. We request that eggs from a proven risk reduction program such as PEQAP be allowed to be labeled with alternate safe handling instructions rather than requiring the warning label. To require a warning label will send a "threatening or negative" message that would serve to negate PEQAP's strict food safety protocol from the standpoint of consumer perception. As a matter of fact, there should be a "positive" label system adopted by FDA that would recognize PEQAP produced eggs.

It is respectfully requested that senior FDA officials have the opportunity to meet with our professional food safety staff and poultry industry officials to discuss our internationally recognized PEQAP protocol with the view that this is better protection than a warning label.

Thank you for considering this request. I respectfully await your reply.

With warm personal regards, I remain

Sincerely,

A handwritten signature in black ink, appearing to read "Sam Hayes Jr.", with a stylized, cursive script.

SAMUEL E. HAYES, JR.

CROSS FILE SHEET

File Number:

98N-1230/ *LET 2*

See File Number:

97P-0197/ *LET 2*

96P-0418/ *LET 3*